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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,006	09/14/2000	Patrick K Sullivan	OCEANIT	9060

7590

11/29/2001

James C Wray
1493 Chain Bridge Road
Suite 300
McLean, VA 22101

EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 11/29/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/662,006

Applicant(s)

SULLIVAN ET AL.

Examiner

Patricia C. Mallari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

The drawings are objected to because many of them contain images so unclear that it is impossible to discern any characteristics of the images. Correction is required.

Specification

The abstract of the disclosure is objected to because "has" in the first line should read "have"; there should be a comma after "signals" in the third line. Correction is required. See MPEP § 608.01(b).

The use of the trademarks MEDEVAC and LABVIEW has been noted in this application. They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 2 and 12 are objected to because of the following informalities: "a" in the second line of claim 2 and the first line of claim 12 should be deleted. Appropriate correction is required.

Claim 44 is objected to because of the following informality: "the sensor" or "it" should appear between "positioning" and "on" in the second line of the claim.

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Claim 45 is objected to because of the following informality: "further" should appear before "comprising" on the first line of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 35 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 35 includes ceramics, hydrophones, microphones, and pressure transducers, in addition the polyvinylidene fluoride sensors claimed in claim 4, upon which claim 35 is ultimately dependent. The specification lacks adequate description of the inclusion, as well as the function, of these additional sensors.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, 8, 9, 10-26, 28, 30, 31, 33, 35 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the polymer" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim because "a polymer" is claimed in claim 3, while claim 4 is dependent upon claim 2.

Claim 8 recites the limitation “the signals” in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim, since claim 8 is dependent upon claim 7, which lists several different types of signals. It is unclear whether the different signals in claim 8 fall under each grouping set forth in claim 7, or whether the signals each fall under a different group. Further, it is unclear whether the invention, as set forth in claim 8, senses *all* signals listed under that claim or may optionally sense the listed signals provided in the claim.

Claim 14 recites the limitation “the band-pass filter” in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim, because “one band-pass filter” is claimed in claim 5, while claim 14 is dependent upon claim 6, subsequently dependent upon claim 4.

Claims 28 and 33 contain the trademark/trade name MEDEVAC in the third line of claim 28 and the first line of claim 33. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe litters and, accordingly, the identification/description is indefinite. Furthermore, claim 28 recites the limitation “the

substrate” in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites “by placing the at least one sensor on a body”; claim 18 recites, “wherein the film is positioned under the body”; claim 19 recites “wherein the film is positioned on the body”; and claims 30 and 31 recite “wherein the plural sensor measure . . . at plural locations on the body”. In all cases the body is non-statutory subject matter and therefore cannot positively be claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 13-15, 18, 27, 28, 32, 36, 37-41, 44, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Snyder et al. Snyder teaches a multi-channel ventilation monitor having two acoustic sensors (microphone array) and a motion sensor, preferably polyvinylidene fluoride (PVDF) film incorporated into a mattress. The

motion sensor may also be incorporated into a harness to be worn by a patient. An additional channel may be added to the system to process signals from a temperature sensor. The electrical signals from the sensors are amplified, processed through band pass filters, and converted into digital quantities by an analog to digital converter. The digital signals are communicated to the microprocessor for signal analysis. The monitor also includes a display to show data indicative of the microprocessor activities (figs 1a-d). In regard to the method claims, the details of the apparatus disclosed characterize the method of using it. As to the language in claims 36 and 46, applicant should note that this is merely "intended use" language, which cannot be relied upon to define over Snyder et al., since Snyder discloses all of the claimed steps (elements) and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647.

Claims 1-8, 14-17, 36-39, 42-44, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Zanetti et al. Zanetti describes a device to sense cardiac compression waves including an accelerometer 22, comprising a piezoelectric crystal 27 which may be substituted with piezo-film, such as polyvinylidene fluoride. Amplifier 34 amplifies the analog signal from film 27. The signal is then applied to band pass filter 38, and the band limited analog signal proceeds to an analog to digital converter 41. Various electrical apparatuses and computer software may be utilized for processing the signal. A Fourier analyzer 61 employing a Fourier transform algorithm eventually analyzes the digital signal, and display means 63 may show a graph or other data derived from analysis of the signal (Figs. 3 & 4). Output from the analysis may be stored on computer tape, disk storage, or other magnetic media.

Claims 1, 2, 27, 32, 36-38, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by McQuilkin. McQuilkin describes a blood pressure monitor 2 with sensor unit 12 composed of proximal velocity sensor 14 and distal velocity sensor 16, both of which are piezoelectric transducers to obtain flow velocity signals. Sensors 14 and 16 are connected to frequency processing circuits 20A through 26 A and 20B through 26B which filter, identify, align and average the signals associated with each cardiac cycle. Display 38 includes graphical display screen 104, chart recorder 106, and digital display 108 and shows all pertinent information derived from the signals from sensors 14 and 16 by circuitry 20A and B through 28A and B, as well as by waveform generator 30 and calibration circuit 32 (Fig. 1B).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. in view of Crawford. Snyder teaches a multi-channel respiration monitor including several sensors, one of which may be comprised of PVDF film incorporated into a mattress or onto a harness to be worn by a patient. The sensors communicate to a microprocessor and the results are displayed for the user. However, Snyder is silent as to the construction of the mattress. Crawford discloses a respiration monitor comprising a pad with a plurality of strip-like elements 6 of piezoelectric film, such as PVDF. Foam

layers 3 may be applied to both sides of the pad. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the mattress of Crawford with the monitor of Snyder in order to make the sensor comfortable for a patient to use.

Claims 10 and 11 are rejected under 35 U.S. C. 103(a) as being unpatentable over Snyder et al. in view of Scanlon. Snyder teaches a multi-channel respiration monitor including several sensors, one of which may be a piezoelectric transducer comprised of PVDF film incorporated into a mattress. The sensors communicate to a microprocessor and the results are displayed for the user. Snyder is silent as to the construction of the mattress, however. Scanlon discloses a sensor pad 12 placed in a crib, incubator, bed, or the like which is connected to a monitoring and sensing system 13. The pad is characterized as a mattress with an interior fluid chamber 12a containing a substance such as air or water; a sheet or multiple strips of piezoelectric film may be used in conjunction with the pad 12 (figs. 1 and 2). Therefore, it would have been obvious to combine the mattress of Scanlon with the monitor of Snyder in order to make the pad comfortable for the patient as well as to enhance the pressure signals of the mattress.

Claims 19, 20, 25, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. in view of Crawford. Trimmer teaches a blood pressure and pulse rate measuring apparatus. The apparatus has a sensor head 12 including first and second piezoelectric transducers positioned on the upper arm of a patient via a cuff, as shown in Figure 2, and coupled to electronic computation display

module 16 via cable 14. First and second transducers of sensor head 12 measure the rise time at their respective positions and calculate the pulse wave transit time from the rise times (PWTT) (figs. 2 and 7). Module 16 receives the electrical outputs from cable 18 through low pass filters 20 and 22, which are coupled in series with amplifiers 24 and 26. Trimmer lacks PVDF film as the transducers in the sensor head. However, Crawford teaches a mattress employing PVDF film as piezoelectric elements. Therefore, it would have been obvious to use the PVDF film of Crawford as the piezoelectric transducers of Trimmer et al. since it is known that PVDF exhibits piezoelectric properties and is often used as a piezoelectric transducer.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trimmer et al. in view of Crawford, as applied to claims 19, 20, 25, and 31, above, and further in view of Zomer and Isaacson et al. Trimmer, as modified, lacks a radio frequency (RF) filter connecting the cable and the film. Zomer describes an apparatus comprising two piezoelectric transducers 7a and 7b. Electrical leads 5a and 5b attach transducers 7a and 7b, respectively, to a well-known filter. The resulting signal travels via output wires 33a and 33b to a cable leading to a recorder (Figs. 2 and 9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the filter of Zomer with the blood pressure and pulse wave apparatus of Trimmer et al. in view of Crawford in order to eliminate noise, since it is well-known that piezoelectric material is susceptible to static.

However, Zomer is silent as to the specific cut-off frequency of this filter.

Isaacson teaches a pulse oximeter 10 wherein a sensed signal waveform is applied to a

suitable radio frequency RF low-pass filter 32 used to filter out any radio frequency interference which might be present in the environment in which the system may be used (fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine Isaacson et al. with the blood pressure and pulse wave apparatus of Trimmer in view of Crawford and Zomer, in light of the well-known susceptibility of piezoelectric material to noise, in order to eliminate noise which the apparatus is likely to encounter, such as RF interference generated by electrocautery equipment in an operating room.

Claim 24 is rejected under 35 U.S. C. 103(a) as being unpatentable over Trimmer et al. in view of Crawford, Zomer, and Isaacson et al., as applied to claims 21-23 above, and further in view of McQuilkin. Trimmer, as modified, lacks an oscilloscope and chart recorder. However, McQuilkin discloses a blood pressure monitor 2 with two piezoelectric transducers 14 and 16 connected to frequency processing circuits 20A through 26 A and 20B through 26B and a display 38. Display 38 includes a graphical display screen 104, such as a cathode ray tube, a chart recorder 106, and a digital display 108 (Fig. 1B). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the blood pressure monitor of McQuilkin with the blood pressure and pulse wave apparatus of Trimmer in view of Crawford, Zomer, and Isaacson et al. in order to provide the user with the option of continuously monitoring the waveform with or without a hard copy.

Claims 25, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over McQuilkin in view of Crawford. McQuilkin describes a blood pressure

monitor 2 with sensor unit 12 composed of proximal velocity sensor 14 and distal velocity sensor 16, both of which are piezoelectric transducers to obtain flow velocity signals. Sensors 14 and 16 are connected to frequency processing circuits 20A through 26 A and 20B through 26B which filter, identify, align and average the signals associated with each cardiac cycle. Display 38 includes graphical display screen 104, chart recorder 106, and digital display 108 and shows all pertinent information derived from the signals from sensors 14 and 16 by circuitry 20A and B through 28A and B, as well as by waveform generator 30 and calibration circuit 32 (Fig. 1B). McQuilkin lacks PVDF film as the sensors. However, Crawford teaches a mattress employing piezoelectric elements, wherein PVDF film is used as the piezoelectric elements. Therefore it would have been obvious to use the PVDF film of Crawford as the piezoelectric transducers of McQuilkin since it is known that PVDF exhibits piezoelectric properties and is often used as a piezoelectric transducer.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. in view of Scanlon. Snyder teaches a multi-channel respiration monitor including several sensors, one of which may be a piezoelectric transducer comprised of PVDF film incorporated into a mattress. The sensors communicate to a microprocessor and the results are displayed for the user. Snyder lacks a sensor with a wireless communication setup. However, Scanlon teaches a sudden infant death syndrome (SIDS) monitor including a sensor pad 12, which may include piezoelectric transducers (Fig. 1). The output from pad 12 may be transmitted via transmitter 50 to a remote location via receiver 52 (Fig. 3). Therefore it would have been obvious to one of

ordinary skill in the art to combine the SIDS monitor of Scanlon with the monitor of Snyder et al. in order to allow the sensed information to be transmitted to a doctor or medical personnel for diagnosis or treatment.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snyder et al. Snyder teaches a multi-channel respiration monitor including several sensors, one of which may be a piezoelectric transducer comprised of PVDF film incorporated into a mattress. The sensors communicate to a microprocessor and the results are displayed for the user. Snyder lacks incorporating the array of sensors into a litter. However, it would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the sensors of Snyder into a litter. The embodiment of Snyder incorporating the sensor(s) into a mattress suggests monitoring a patient lying down; this motivation further translates into monitoring a patient in other situations where he or she may be lying down, such as in a litter, for example.

Allowable Subject Matter

Claim 26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 4,537,200 to Widrow.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Mon-Fri 8:30 am-6:00 pm (alternate Fri. off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Nasser can be reached on (703) 308-3251. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

pcm
November 13, 2001

Patricia C. Mallari

Robert L. Nasser
ROBERT L. NASSER
PRIMARY EXAMINER